

## REMARKS

Claims 1, 3-5, 12-15 and 21-34 are presently pending in the case. Claims 1, 21, 25 and 29 have been amended. The amendments are supported by the specification as originally filed. For example, see original claim 11, page 7 lines 23-25, page 6 line 26-30 and Tables 4 and 5. Claim 11 has been cancelled.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 1, 3-5, 11-15 and 21-34 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,934,273 to Anderson et al (hereinafter Anderson et al) in view of PCT Publication WO 96/32096 to Eljamal et al (hereinafter Eljamal et al), U.S. Patent No. 5,855,913 to Hanes et al (hereinafter Hanes et al) and U.S. Patent No. 5,049,389 to Radhakrishnan (hereinafter Radhakrishnan), as evidenced by Swarbrick et al. The rejection is traversed.

Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al do not render independent claim 1, for example, unpatentable. Claim 1 is to a method for the pulmonary administration of a dry powder composition comprising, *inter alia*, loading the dry powder composition into a passive dry powder inhaler and administering the dry powder composition from the inhaler to the respiratory tract of a patient, wherein the lung deposition is greater than 25% for flow rates from 10 to 60 liters per minute. Anderson et al does not disclose the method as set forth in claim 1. Anderson et al discloses administering a dry powder composition using a Turbuhaler dry powder inhaler. As can be seen in Applicants Example 2, the present invention is superior to compositions, such as Anderson et al's that are administered with a Turbuhaler. As shown in Table 2, lung deposition using a Turbuhaler is 15% at a flow rate of 35 liters per minute. Thus, the Turbuhaler administered composition does not provide a lung

deposition of greater than 25% for flow rates from 10 to 60 liters per minute. Accordingly, Anderson et al does not disclose all features of claim 1 and does not render the claim unpatentable.

The other references do not make up for the deficiencies of Anderson et al. Anderson et al does not disclose a pulmonary administration using a passive dry powder inhaler wherein the lung deposition is greater than 25% for flow rates from 10 to 60 liters per minute. Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al are not relied on to make up for this deficiency in Anderson et al, nor do they. Accordingly, no reference or combination of references arrives at an administration as recited in claim 1. Accordingly, the Examiner has not established a prima facie case under 35 U.S.C. §103(a).

For at least these reasons, claim 1 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Anderson et al in a manner that would result in the invention of claim 1, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 1 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 3-5 and 12-15, which depend from claim 1 and are not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al for at least the same reasons as claim 1.

In addition, independent claim 21 is not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al. Claim 21 is to a

method for the pulmonary administration of a dry powder composition comprising, *inter alia*, providing a dry powder composition, loading the dry powder composition into a passive dry powder inhaler, and administering the dry powder composition from the inhaler to the respiratory tract of a patient, wherein the fine particle fraction (FPF<sub>4+F</sub>) emitted from the inhaler is at least 60%. Anderson et al discloses administering a dry powder composition using a Turbuhaler dry powder inhaler. However, there is no evidence to suggest that the administered powder from Anderson et al would have a fine particle fraction of at least 60%. To the contrary, one of ordinary skill would expect the fine particle fraction to be significantly less than 60%. Accordingly, Anderson et al does not disclose all features of claim 21 and does not render the claim unpatentable.

The other references do not make up for the deficiencies of Anderson et al. Anderson et al does not disclose a pulmonary administration using a passive dry powder inhaler wherein the fine particle fraction is at least 60%. Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al are not relied on to make up for this deficiency in Anderson et al, nor do they. Accordingly, no reference or combination of references arrives at an administration as recited in claim 21. Accordingly, the Examiner has not established a *prima facie* case under 35 U.S.C. §103(a).

For at least these reasons, claim 21 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Anderson et al in a manner that would result in the invention of claim 1, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 21 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 21 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 22-28

which depend from claim 21 and are not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al for at least the same reasons as claim 21.

Independent claim 29 is not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al, either. Claim 29 is to a method for the pulmonary administration of a dry powder composition comprising, *inter alia*, providing a dry powder composition, loading the dry powder composition into a passive dry powder inhaler, and administering the dry powder composition from the inhaler to the respiratory tract of a patient, wherein the fine particle fraction (FPF<sub>4+5</sub>) emitted from the inhaler is at least 60%. Anderson et al discloses administering a dry powder composition using a Turbuhaler dry powder inhaler. However, there is no evidence to suggest that the administered powder from Anderson et al would have a fine particle fraction of at least 60%. To the contrary, one of ordinary skill would expect the fine particle fraction to be significantly less than 60%. Accordingly, Anderson et al does not disclose all features of claim 29 and does not render the claim unpatentable.

The other references do not make up for the deficiencies of Anderson et al. Anderson et al does not disclose a pulmonary administration using a passive dry powder inhaler wherein the fine particle fraction is at least 60%. Eljamal et al, Hanes et al, Radhakrishnan, and Swarbrick et al are not relied on to make up for this deficiency in Anderson et al, nor do they. Accordingly, no reference or combination of references arrives at an administration as recited in claim 29. Accordingly, the Examiner has not established a prima facie case under 35 U.S.C. §103(a).

For at least these reasons, claim 29 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Anderson et al in a

manner that would result in the invention of claim 1, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 29 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 29 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 30-34 which depend from claim 29 and are not rendered unpatentable by Anderson et al, Eljamal et al, Hanes et al, Radhakrishnan and Swarbrick et al for at least the same reasons as claim 29.

### **Claim rejections under judicially created doctrine of Double Patenting**

The Examiner provisionally rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 10/141,219 in view of Anderson et al and Hanes et al.

The Examiner provisionally rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 11/187,757 in view of Anderson et al and Hanes et al.

The Examiner rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent No. 7,306,787 in view of Anderson et al.

The double patenting rejections will be taken up and the appropriateness of filing a terminal disclaimer will be determined upon the indication of otherwise allowable claims.

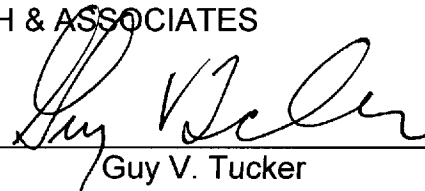
## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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